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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,885	03/01/2004	Richard Kaplan	086524-0010	2598
8668 7590 07/08/2008 DRINKER BIDDLE & REATH LLP ATTN: PATENT DOCKET DEPT. 191 N. WACKER DRIVE, SUITE 3700 CHICAGO, IL 60606				
EXAMINER COLQUITT, AARON BRUCE				
ART UNIT 3735		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,885

Applicant(s)

KAPLAN ET AL.

Examiner

AARON B. COLQUITT

Art Unit

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71 is/are allowed.
- 6) ☒ Claim(s) 38-43, 45-70 and 72-76 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment dated March 7, 2008. The examiner acknowledges the amendments to claims 38, 47, 48 and 55, and the addition of claims 73-76. Claims 38-76 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 45 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 45 recites the limitation "method of claim 44" in line 1. There is insufficient antecedent basis for this limitation in the claim.
5. Claim 72 recites the limitation "method of claim 71" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 38-41, 43, 46-54, and 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5928199 to Halyak (hereinafter "Halyak") in view of US 5999846 to Pardey et al. (hereinafter "Pardey").

Halyak teaches (in ref 38) an automated system for facilitating the implementation of behavioral therapy that uses information indicative of a subject's wake/sleep state to improve the subject's sleep or sleep hygiene, comprising:

passive wake/sleep determination means for producing information indicative of the subject's wake/sleep state (column 2, lines 49-58) and means for implementing the steps of the behavioral therapy utilizing the wake/sleep information (column 4, lines 11-24).

A combination of therapies (in ref 39-51, 43, and 46) is taught in column 2, line 59 to column 3, line 3, wherein information of the stimulus and restriction/relaxation are used. This system also uses EEG's, heart rate, movement sensors, galvanic skin response, and other parameters for sleep research (column 3, lines 58-67), where the user can calibrate the values that are most efficacious for the user (column 5, lines 10-15).

The apparatus (in ref 47) processes information taken from the group consisting of: EEG, EKG, EMG, EOG, actigraphy, body movement, galvanic skin response, respiratory changes, eye movements and combinations of two or more thereof to determine the subject's wake/sleep state; and means for implementing the

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behavioral therapy utilizing the wake/sleep state information (column 3, line 58 to column 4, line 55).

Halyak teaches (In ref 48-54, 58-69) that the use of an apparatus that can record varying resistance values can determine when a user should be woken up and that time can be calibrated (column 4, lines 38-42 and column 3, lines 27-33) to the user's needs (column 5, lines 1-15) over a length of time (column 4, lines 10-13) that can be viewed on a monitor or printed for a record of the sleep session (column 4, lines 11-24). The apparatus is capable of being worn by the user (column 4, lines 5-10) and can wake the user with an alarm (column 5, lines 20-23) that alerts the user either after the sleep period has been completed (column 5, lines 16-34) or as a failsafe.

Halyak however fails to teach of the sleep monitoring device being used to assist those suffering from insomnia.

Pardey teaches a physiological monitor that displays a summary index which provides a simple objective indicator of the degree of insomnia suffered by the subject. The device is worn by a subject during the night, during which time the apparatus continually acquires and analyses an EEG signal from the subject's scalp. The insomnia monitor comprises:

- (1) one or more electrodes for obtaining an electrical signal from a subject over a period of epochs, the electrical signal being related to the sleep stage type being experienced by the subject;
- (2) a processor adapted to analyze the electrical signal and assign a sleep stage type to each epoch to generate a hypnogram;
- (3) means for analyzing the hypnogram to generate a summary index of sleep quality over the period of epochs; and

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(4) means responsive to the means for analyzing the hypnogram to display the summary index of sleep quality (col. 1, line 55 to col. 2, line 8).

The hypnogram or Wakeogram may be generated from a plurality of electrical signals (eg. EEG) and may be stored and analyzed at the end period of monitoring. The insomnia monitor separates levels of awake and sleep and states into Wakefulness, Dreaming/Light Sleep and Deep Sleep. These correspond to the human-scored stages of Wake, REM/Stage 1 and Stage 4. Wakefulness can be further partitioned into different degrees of Wakefulness or Vigilance, such as Active Wake, Quiet Wake, Wake with high alpha content, Wake with high theta content (col. 4, lines 43-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a sleep monitoring system similar to that of Halyak with an insomnia monitor similar to that of Pardey in order to provide for a system that separates the levels of sleep of an individual and provides proper treatment to the patient based on their wake/sleep state.

8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak and Pardey as applied to claim 38 above, and further in view of US 5573013 to Conlan (hereinafter "Conlan").

Halyak and Pardey teach a system that facilitates the treatment of insomnia but fails to mention the use of drug therapy in addition to the dependent treatments. Conlan, however, teaches (column 1, lines 26-36) that by observing body movement information useful to physicians and researchers can be found, for

example, by observing a subject's movements, the occurrence and length of natural phenomenon, such as wakefulness, rest and sleep can be determined. By observing the nature of a subject's movement, the occurrence and severity of disorders and the effects of drugs can other therapy can be accessed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an automated behavioral therapy system similar to that of Halyak and Pardey with a system that analyzes the effects of drug therapy on sleep similar to that of Conlan to develop a therapeutic treatment that uses drug therapy to influence sleep in order to enhance the sleep quality of the patient.

9. Claims 55-57, 70, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halyak and Pardey as applied to claim 38 above, and further in view of US 2002/0067273 to Jaques et al. (hereinafter "Jaques").

Halyak and Pardey teach a system that facilitates the treatment of insomnia but fail to teach providing information as to whether a subject is in bed or not or providing instructions to the patient after exiting the bed.

Jaques however teaches a patient monitoring system that comprises a bed with a low-cost pressure pad placed under the patient's buttocks but may be placed anywhere else that will generate weight related signals, such as under the shoulders of the patient. In either case, a voice message may be played requesting the patient to remain in the bed or instructions may be given to the patient and/or an alarm may be transmitted.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an automated system similar to that of Halyak and Pardey with a system that tracks and alerts a patient of their in-bed status similar to that of Jaques in order to implement a therapy that encourages a patient to associate the bed as the place used only for sleeping and aid in insomnia treatment.

Allowable Subject Matter

10. Claim 71 is allowable over the prior art of record.

No prior art of record teaches or fairly suggests an apparatus including means for implementing a stimulus control therapy that utilizes sleep/wake information and applies the rules recited in claim 71.

11. Claims 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

No prior art of record teaches or fairly suggests an apparatus including means for implementing a stimulus control therapy having the rules recited in claim 44.

12. Claims 45 and 72 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments, see page 9, filed March 7, 2008, with respect to the rejection(s) of claim(s) 38-41, 43 and 46 under 102(b) alleging that Halyak does not teach the treatment of insomnia have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly applied art of Pardey.

14. Applicant's arguments, see pages 9-10, filed March 7, 2008, with respect to the rejection(s) of claim(s) 55-57 and 70 under 103(a) alleging that Halyak in view of Wyatt does not teach if a subject is in bed have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly applied art of Jaques.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON B. COLQUITT whose telephone number is (571)270-1991. The examiner can normally be reached on Monday-Friday 7:30 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/A. B. C./
Examiner, Art Unit 3735